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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/599,660	06/22/2000	Jorg G. Moser	BJA243A	7532

7590 03/06/2003

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EXAMINER

GUPTA, ANISH

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 03/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/599,660	MOSER, JORG G.	
	Examiner	Art Unit	
	Anish Gupta	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-8 and 11-23 is/are pending in the application.
- 4a) Of the above claim(s) 5,7,11,13,16 and 17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-6,12,14,15 and 18-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment filed 12-16-02 is acknowledged. Claims 1-2, 4, 8, 12, and 17 were amended by the Amendment. Claims 1-8 and 11-23 are pending in this Application.

Election/Restriction

1. Applicants argue that "[t]he examiner has apparently changed the election agreed upon with the applications, simply because no prior art was found." Applicants contend that allowability of the chemotherapeutic compound bacteriopheophorbide or pheophorbide containing complexes should have been indicated before proceeding to the "alternative aspects of the invention based on chemotherapeutic species." Applicants assert that "[t]he delay in replying to this action reflects in part this attorney's initial disbelief that what the examiner has done was withdraw the specifically chosen/elected species that the applicants had made." Applicants also state that if claims based on the photosensitizer compound as the therapeutic compound, "then the proper search expansion should have been to drop the optional spacer structure first do a search again." Applicants further describe the search strategy that should have been taken in the office action. Applicants conclude "[t]he search sequence apparently followed by the examiner has no basis in the agreement or written and oral wishes of the applicants as expressed by their representative, the attorney whose signature appears on all correspondences with the Patent Office."

As a formal matter, if Applicants were having problems with the Office Action, the Applicants could have easily placed a phone call to the Examiner to get any clarification. The record already indicates that the Examiner place a telephone call on August 7, 2002 to further prosecution after Applicant's improper election to the Election of Species requested 9-17-01.

As for the substantive issues, Applicants are requested to review the Election of Species procedure as set forth in the chapter 800 of the MPEP. Under Election of Species procedure, Applicants are required to elect a Single Disclosed Species. See generally 809.02(a). Applicants do not provide a catalogue of species that they would desire to have searched. Thus, under this Election of Species, a search **must** be conducted for the elected species. However, beyond the elected species, the **discretion** in the search strategy for the search of the broad markush group is placed on the examiner. The MPEP does not set forth an contractual obligation between the Examiner and Applicant to conduct a prior art search of the broad markush claim as Applicant's wish for the search to be conducted. With regards to markush practice, the MPEP states:

*"On the other hand, should no prior art be found that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended. If prior art is then found that anticipates or renders obvious the Markush-type claim with respect to a nonelected species, the Markush-type claim shall be rejected and claims to the nonelected species held withdrawn from further consideration. **The prior art search, however, will not be extended unnecessarily to cover all nonelected species.** See MPEP 803.02*

With regards to search strategy the MPEP States:

*"In the examination of an application for patent, an examiner must conduct a thorough search of the prior art. Planning a thorough search of the prior art requires three distinct steps **by the examiner**: (A) identifying the field of search; (B) selecting the proper tool(s) to perform the search; and © determining the appropriate search strategy for each search tool selected." See MPEP 904.02*

In summary, although the MPEP does not specifically state that the search strategy for the extended search of the Markush-type claim is at the discretion of the Examiner, Section 904.02 certainly implies that the appropriate search strategy is at the discretion of the Examiner. In the instant Application, Applicants elected glucosamine as the parachute structure bonded triazine trichloride, the therapeutic structure as bacteripheophorbide and the spacer as the beta amino acid.

Applicants also requested if a search could also be done of the therapeutic structure of pheophrobide. A search was conducted for these species and found to be allowable. Thereafter, the search was extended to the broad Markush group of claim 1, as authorized by MPEP 803.02. Since Applicants elected glucosamine, a search strategy, where the glucosamine was the heart of the search, was conducted. Note that the claims did not specify any preference to any species. Complexes containing glucosamine were found and Applied. In conclusion, the action and search taken in the previous office action is wholly appropriate and well within purview of Election of Species procedure.

Finally, Applicants raised some issues with regards to withdrawn of certain claims, specifically claims 7, 11, 12 and 13. The MPEP states that "[t]he prior art search, however, will not be extended unnecessarily to cover all nonelected species." In the Election of Species procedure, the claims are examined to the extent they read on the elected species. If the elected species is found allowable, as it was in this instant application, the species is held to be allowable not the claim. The search is then extended to the broad markush to determine the patentability of Markush-type claim. If another species is found in the prior art that reads on the Markush type claim, the art is applied to those claims that read on this elected species and the rest of the claims, those that do not read on this species, are held as withdrawn. These withdrawn claims are held as such even though they may have been searched during the initial species search. Again the search and the examination of the claims are based on the species themselves and not the generic as a whole. For these reasons, claims 5, 7, 11, 13 and 16-17 were held as withdrawn. These claims did not read on the species disclosed in Bailly et al.

The Election of Species is appropriate and made FINAL.

This application contains claims 5, 7, 11, 13 and 16-17 drawn to an invention nonelected with traverse in Paper No. 3 and 9. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-4, 6, 8, 12, 14-15, 18-23 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the reasons set forth in the previous office action and the reasons set forth below.

In their response, Applicants made reference to page 6 line 22 through page 7 line 7 and page 5 lines 16-20 of the Specification as to guidance for defining "distance (within the cell) from a cell's membrane."

However, after reviewing these pages for definitions, the specification fails to provide any set definition for a "preselected distance." No numerical values are provided to disclose to one of skill in the art these distances intent to be. Further, the specification does not provide any guidance as to what an ordinary artisan might find to be the desired distance. Accordingly, the claim is indefinite and the rejection is maintained.

In their response, Applicant did not respond to the rejection of claim 4. In claim 4, it is unclear as to what constitutes a specific attachment point to selectins. That is, what radicals in the hydrophilic moiety would be specific attachments points for selectins. Claim is still indefinite.

Note that claims 16-17 were withdrawn from consideration. However to further prosecution, claim 16 and 17 have been examined for possible 112 second paragraph issues even though the claims were held as non-elected.

In their response, Applicant did not respond to the rejection of claim 16 for Second Paragraph issues. In claim 16, there is insufficient antecedent basis for the limitation "said member" in the base claim 5. The problem still exists.

In their response, Applicant did not respond to the rejection of claim 17. In claim 17, it is unclear as to the intended meaning of "region." The claims state that the method is for the destruction of cells. Thus, does the region mean the internal environment of a cell or the external environment of a cell. It is unclear if the administration of the complex via oral routes, such as the mouth, constitutes as part of the "region." The claim is therefore indefinite. The indefiniteness has not been rectified.

In their response, Applicant did not respond to the rejection of claim 17. In claim 17, it is unclear as to the duration of time (seconds, minutes, or hours) that constitute "pretreatment time" since the claim does not provide for a definition of pretreatment time. The claim is still indefinite.

New grounds For Rejections under 112 Second Paragraph

claim 12 was amended to recite "targeting species." However it is unclear what this "species" is to be and what does this "species" target. Further, it is unclear if this "species" is part of the complex and if it is, how it is associated with the complex. That is there a covalent linkage between targeting species and hydrophilic moieties or are there non-covalent associations.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-4, 6, 8, 12, 14-15, 18-23 rejected under 35 U.S.C. 102(b) as being anticipated by Bailly et al. for the reasons set forth in the previous office action and the reasons set forth below.

The claims are drawn to a complex and a method of selective destruction of eukaryotic and prokaryotic cells by using the complex having one parachute structure and one therapeutic compound.

Applicants argue that the glucosamine is not the same as a "di-glucosamine" which can act as a parachute structure. Further, state "[t]he concept of the parachute structure which can regulate to what distance into a cell an active therapeutic compound can enter, is not only taught not taught by the reference, but also is not implied." The reference does not teach a minimum of two glucosamine and the desire to use these molecules. "A mere unit of a glucosamine does not read on the parachute structure nor on the action diameter feature which arises from the structure of the branching and the hydrophilic moieties attached to it."

4. Applicant's arguments filed 12-16-02 have been fully considered but they are not persuasive.

First, the claims do not require that the "parachute" structure be composed of two glucosamine residues. There is no limitation in the claims that would clearly state that the parachute structure is composed of two glucosamine residues. Claim 4 states that the parachute structure can

be sugar monomers. Glucosamine is a sugar monomer and therefore meets the limitation of the claims. With regard to arguments about distance, the complex of the reference would necessarily have the desired distance since all of the structural limitations of the claims are met.

Rejection is maintained.

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (703) 308-4001. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can normally be reached on (703)306-3220. The fax phone number of this group is (703) 308-4242.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Anish Gupta


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SUPERVISORY PATENT EXAMINER
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